Washington State Health Care Authority
Prescription Drug Program
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FINAL DRAFT Minutes of the June 16, 2004 P&T Meeting
[Subject to approval by the committee at the September 15, 2004 meeting]

Committee Attendance:
Daniel Lessler, M.D. (Chair)
Carol Cordy, M.D. (Vice Chair)
Robert Bray, M.D.
T. Vyn Reese, M.D.
Angelo Ballasiotes, Pharm.D.
Alvin Goo, Pharm.D.
Jason Iltz, Pharm.D.
Janet Kelly, Pharm.D.
John White, PA, Pharm.D
Patty Varley, ARNP

Quorum was shown for all Pharmacy & Therapeutics Committee motions, 2nd's, and votes.

9:00 a.m. - Committee came to order.

× Review of changes to March 17th, 2003 P&T Committee meeting minutes.

Motion: [Lessler] To accept the meeting minutes of March 17th P&T Meeting Minutes.
2nd : Yes
Vote: Unanimous; Yea

Clarification of Estrogen regarding Dosage:

× Marcia Coleman, M.D. for U.S. Medical Communication commented that Premarin allows a wider range of dosing than Estradiol and does not need to be subject to alternate daily dosing or split tablets.

Motion: [Iltz] I move to ratify and clarify the Committee's December 17th, 2003 motion and recommendation as follows: Conjugated Equine Estrogen (oral), Conjugated Equine Estrogen (vaginal), Conjugated Estrogen Synthetic, Esterified Estrogen, Estradiol (oral), Estradiol (vaginal), and Estropipate are shown to be equally efficacious in the treatment for the indication of Menopausal Symptoms. There is insufficient evidence available at this time to the committee to compare the relative safety of the above named estrogen products.

In conjunction with the above stated motion it is the Committee's recommendation that practitioners prescribe the lowest effective dose of the particular estrogen product prescribed.
2nd
Vote: Unanimous, Yea

Beta Blockers Clarification:

- Jeff Graham, M.D. consultant for the Prescription Drug Program stated that a re-review found that the committee made the correct decision supported by the evidence. Concerns voiced by Washington state practitioners and GlaxoSmithKline had been forwarded to the Evidence-based Practice Centers and their updates for Beta Blockers will be made available for review by the December meeting at which point the committee will review this drug class again. Marian McDonough, PharmD. for Oregon Health and Sciences University gave a slide review of
  Calcium Channel Blockers. (via phone conference)

Calcium Channel Blockers

- Marian McDonough, PharmD. for Oregon Health and Sciences University gave a slide review of Calcium Channel Blockers. (via phone conference)
- An Pham for Reliant Pharmaceuticals commented on Dyncirc CR versus amlodipine citing a study conducted by Michael Gantz of the Cleveland Clinic showing Dynacirc CR as the cause of blood pressure lowering in patients who cannot tolerate amlodipine due to pedaldemia..
- Roy Palmer for Pfizer commented on the use of Norvasc (amlodipine) mentioning a large trial published last week noting no drug interaction, a long half life, crushable tablets and good insulin interaction..
- Alvin Goo, Pharm.D. expressed concern regarding the treatment of Congestive Heart Failure and Angina with dihydropyridine and amlodipine.
- T. Vyn Reese, M.D. commented that only amlodipine had been tested with Angina and any patient with dual complications of both Congestive Heart Failure and Angina would need a prescription of amlodipine.
- Robert Bray, M.D. commented that while he can offer no opinion on the last review he does feel that it would be in the best interests of the committee to maintain the balance between the two dihydropyridine and the two non-dihydropyridine so as not to exclude anything.
- Wayne Levy, Associate Professor of Cardiology for Pfizer and Nexcare notes studies that show reductions in infarcts versus strokes using amlodipine versus other Calcium Channel Blockers.

  Motion: [Reese] After considering evidence of safety, efficacy and special populations I move that all formulations of generic diltiazem and verapimil be placed on the formulary and that long acting Nifedipine and amlodipine are also on the formulary for the dihydropyridine class. These drugs can be subject to therapeutic interchange on the Washington Preferred Drug List.

- Carol Cordy, M.D. (Vice Chair) commented that the motion seemed premature and needed to be rephrased.
- Daniel Lessler, M.D. (Chair) agreed and commented that Calcium Channel Blockers should be written as two separate classes and should not be therapeutically interchanged between these classes. He also commented on the words safety and efficacy in the body of the motion.

  Motion: [Lessler] After considering the evidence of efficacy and safety I move Calcium Channel Blockers be considered two sub-classes, the dihydropyridines and non-dihydropyridines. All generic forms of verapimil and diltiazem are to be the preferred non-dihydropyridines and Nifedipine XR and Amlodipine are to be the preferred dihydropyridines and all Calcium Channel Blockers can be subject to therapeutic interchange within their respective sub-classes.
  2nd: Reese
  One dissenting vote of Carol Cordy
  Vote: majority, Yea

Non-Steroidal Anti-Inflammatory Drugs

- Mark Helfand, M.D., for the Oregon Health and Sciences University gave a review of Non Steroidal Anti-Inflammatory Drugs (via phone conference)
- Robert Calder, MD with Merck testifies to the GI effects of Vioxx.
- Sean Sigmund comments in regards to meloxicam (Mobic).
- Jill Marie Yanchek, M.D. for Pfizer US Medical urged the committee to consider the use of Cox-II Inhibitors as treatment for arthritis and pain.
- Tess McShane, Director of Communications with the Arthritis Foundation spoke as both an advocate for the arthritic as well as an arthritis sufferer. Urged committee to include Cox-II on the Washington Preferred Drug List for the management of arthritic pain.
- Dr. Toomey commented on the committee overlooking the surgical use of the NSAID class.
- Robert Bray, M.D. commented that while celacoxib is not as safe for GI indication as robicoxib, robicoxib is more risky in treating cardiovascular problems. Noting that there are good arguments for using Cox-II for patients on Warfarin with bleeding problems and that individualized problems could be handled in other ways. He also moved for separate motions for Non Selective NSAIDs and Cox-II Inhibitors, both of which are equally efficacious in the treatment of chronic pain

  Motion: [Lessler]After considering evidence of safety, efficacy, and special populations I move that traditional non-steroidal anti-inflammatory drugs have similar efficacy and safety and can be subject to therapeutic interchange in the Washington preferred Drug List.
  2nd
  Vote: Unanimous, Yea

- Angelo Ballasiotes, Pharm.D. commented that by excluding Cox-II's from the motion the committee limits themselves.

  Motion: [Lessler] I vote that Cox-II inhibitors are equally efficacious with traditional NSAIDs. However, there is insufficient evidence to establish the safety of Cox-II inhibitors in relation to each other to traditional NSAIDs. Cox-II inhibitors should not be interchanged with traditional NSAID's nor with each other. The committee finds that carisoprodol is a medication that is subject to abuse and therefore its use is not recommended.
  2nd: Yes
  One Dissenting vote of Alvin Goo
  Vote: majority Yea, motion passes

  Motion: [Varley] I move to rescind the first motion
  2nd: Reese
  Vote: Unanimous, Yea

  Motion: [Lessler] I move to table the second motion and make plans to revisit this motion in September
  2nd: Robert Bray
  Vote: Unanimous, Yea

Ace Inhibitors

- Roger Chou M.D. of the Oregon Health and Sciences University gave a full review (via phone conference)
- Ann Simons commented on the current appropriate use of Altace within the medical community using the Washington State Preferred Drug List.
- Siri Childs, Pharm.D. commented that a new drug, Benazipril, has been added to the Ace Inhibitor class and has not been voted on.

Motion: [Reese] After considering evidence of safety and efficacy I move that ACEI are effective and safe and can be subject to TIP. Ramipril may be made available to patients meeting HOPE study criteria.
2nd:
Vote: Unanimous, Yea

Long Acting Opioids

- Roger Chou, M.D. of the Oregon Health and Sciences University gave a full review (via phone conference)
- Dr. Stuart Dupen of Swedish commented that with all emergency room visits and intredegal pumps considered as well as time used to administer oral medications the duragesic patch is more cost effective as a preferred drug.
- T. Vyn Reese, M.D. commented that non preferred medication is available when the provider is an endorsing practitioner of the Therapeutic Interchange Program and indicates dispense as written on the prescription.
- Donna Marshall, PharmD with UMP commented that while a dispense as written indication on a prescription does prevent the need for Prior Authorization on certain medications it does not override the need for Prior Authorization on specific quantity limits on certain medications.
- Jaymie Mai, Pharm.D. with the Department of Labor and Industries explained that while LNI does have a WAC associated with duragesic which is a non-covered drug if a patients meets the criteria as stated by the FDA this drug will be made available to them.
- Stuart Rosenblum, M.D. for Legacy Health Systems testified that there has been a 400% increase in methadone death associated with the prescription of methadone and advises against the inclusion of this drug on the Washington State Preferred Drug List.
- Darrell Smith with Johnson and Johnson on behalf of Bill Struyk, commented that in a review by the new England Journal of Medicine evidence now suggests that prolonged, high dose opioid therapy may be neither safe nor effective.

Motion: [Lessler] After considering the evidence available on safety, efficacy and use in special populations, I move that the Long Acting Opioids are safe and effective, when used appropriately and have similar adverse effects. There should be more than one preferred drug in the long acting opioid class.
2nd : Yes
Vote: Unanimous; Yea

- Dan Lessler, M.D. postponed the discussion of the Therapeutic Interchange Program will be moved to the September meeting.

4:00 p.m. - Pharmacy & Therapeutics Committee Adjourned

DUR Board Meeting Minutes
June 16, 2004

WASHINGTON STATE PHARMACY AND THERAPEUTICS COMMITTEE MEETING
Regular Meeting
Holiday Inn SeaTac

2:45pm – 4:00pm

Council Members Attending: Alvin Goo, Pharm D, Patti Varley, ARNP, Carol Cordy, MD, Dan Lessler, MD, Robert Bray, MD, T. Vyn Reese, Angelo Ballasiotes, Pharm D.,
Jason Iltz, Pharm D., Janet Kelly, Pharm D., and John White, PA,

Medical Assistance Administration, Coordinating Staff and Guests: Jeff Thompson, MD, MAA Chief Medical Officer; Joan Baumgartner, MD, MAA Medical Consultant; and Siri Childs, Pharm D, Pharmacy Policy Manager, MAA

Observers: Rob Hedquist, Pfizer, Bobbi Jo Drum, Pfizer, Dr. Stuart Rosenblum
Tony Jelinek, Andrx, Kara Smith, Boehringer-Ingeheim, Sean Sigmon, Boehringer-Ingeheim, Barry Benson, Merck, Gary Scheider, Novartis

I. ADMINISTRATIVE ITEMS

The meeting was brought to order by Chairman, Dan Lessler, MD. The minutes of the previous DUR Board Meeting on March 17, 2004 were approved. The members of the Washington DUR Board introduced themselves.

II. "EVIDENCE-BASED MEDICINE: COX II INHIBITORS…..FINDING THE VALUE"

Dr. Lessler welcomed Jeff Thompson, MD, Chief Medical Officer/Director of Medical Management, Medical Assistance Administration who gave a presentation entitled, "Evidence-Based Medicine: Cox II inhibitors…..Finding the Value". (See attached) Dr. Thompson's presentation covered the following:

- Review of the DUR Function and PA rules/principles
- MAA's Utilization and Costs of Cox II inhibitors
- OHSU's evidence-based reviews of Cox II inhibitors in terms of safety, effectiveness, and use in special populations
- Review of current EPA criteria
- Proposed new strategies that would balance access, quality, and cost.

Dr. Thompson's presentation included slides that showed the market shift of the preferred drug classes implemented by MAA. Dramatic market shifts were seen in the Triptan and LA Opioid drug classes when prior authorization was required for non-preferred drugs.

The NSAID drug class, including the Cox II inhibitors, has been managed via the Expedited Prior Authorization (EPA) program since 1999 and MAA has 40% utilization of Cox II inhibitors. Kaiser has benchmarked their use at less than 5% which is consistent with the OHSU EPC reports that show little if any advantage (safety) to using the high cost Cox II inhibitors over the non-selective NSAIDS.

Dr. Thompson delineated the current EPA process which requires that the client does not have a history of a GI bleed or ulcer, and prescriptions for a Cox II inhibitor must meet specific criteria for indication, dosing, and duration of therapy.

Dr. Thompson described the process that prescribers would follow when ordering Cox II inhibitors after July 1, 2004. Dr. Thompson proposed that all prescribers, endorsing or non-endorsing must meet the EPA criteria that states that the client does not have a history of a GI bleed or ulcer when ordering any NSAID, even Cox II inhibitors. Additionally, those prescriptions for Cox II inhibitors must meet more criteria: must have tried and failed two or more generic

NSAIDs, and must meet all the criteria for appropriate indication, dosing and duration of therapy. Endorsing prescribers meeting the EPA code for no history of GI bleed or ulcer may write "Dispense as written" and have their prescriptions filled for Cox II inhibitors without restrictions. Non-endorsing prescribers must meet the EPA code and then all the other criteria for indication, dose, and duration of therapy.

MAA contracted with Washington State University in 1999 to conduct a pharmacoeconomic study of clients hospitalized while receiving non-selective NSAIDS and Cox II inhibitors. The study results showed that this drug class presents a significant safety concern for Medicaid clients and that the implementation of EPA criteria for safety may be responsible for the decreased hospital admissions for NSAID-related toxicity. The study also demonstrated that clients taking Cox II inhibitors had similar hospital admissions for NSAID-related toxicity and despite the higher cost, did not provide a safety advantage to non-selective NSAIDs in preventing GI and renal serious adverse events.

The Stanford Risk Stratification scale was described by Dr. Thompson which provides a scoring mechanism to quantify risks of NSAID therapy. A score of >20 would indicate substantial risk and would suggest treatment with a low dose narcotic, acetaminophen, or low dose NSAID with a Proton Pump Inhibitor.

Dr. Thompson ended his presentation by asking the DUR Board the question: is the EPA/PA criteria appropriate for MAA to use over the next three months and possibly through the winter as we wait for the next opportunity to review the NSAID drug class?

III. DRUG UTILIZATION REVIEW

Dr. Thompson presented data to the DUR Board showing MAA's Cox II inhibitor utilization compared to the total NSAID Utilization. Cox II inhibitors represent 39% of the prescriptions, 40% of the clients receiving NSAIDS, and 75% of the monthly expenditures in this drug class. If MAA could decrease the prescriptions of Cox II inhibitors to 5% of the total NSAIDs dispensed, taxpayers could save an estimated $8.7 Million.

IV. MANUFACTURERS' PRESENTATION

There were no manufacturers' presentations to the DUR Board during the meeting. Please refer to the June 16, 2004 Pharmacy and Therapeutics Committee meeting minutes (same day) for comments related to the NSAID drug class.

V. STAKEHOLDERS' PRESENTATIONS

There were no stakeholder's presentations to the DUR Board drug the meeting. Please refer to the June 16, 2004 Pharmacy and Therapeutics Committee meeting minutes (same day) for comments related to the NSAID drug class.

VI. RECOMMENDATIONS OF COUNCIL

The DUR Board informally discussed MAA's plan to proceed with the implementation of the NSAID drug class on July 1, 2004 using EPA for all NSAIDs, including Cox II inhibitors to prevent anyone with a history of a GI bleed or ulcer from getting these drugs. Dr. Thompson's procedural questions were answered informally as follows:

- It was generally agreed that any history of GI bleed or ulcer should prevent the use of NSAIDS and Cox II inhibitors;
- Dose limits are important;
- The lowest effective dose should be used
- MAA could also consider history of CHF and kidney disease as well as GI complications as contraindications for NSAIDs, including Cox II inhibitors.
- MAA should go forward with the implantation of the NSAID drug class with EPA for all drugs in the drug class, and PA for brand names drugs and Cox II inhibitors.

ADJOURNMENT

The meeting adjourned at 4:00pm